REMARKS/ARGUMENTS

This is a preliminary amendment in RCE application. The Office Action mailed April 19, 2005 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. The claims presented for examination are: claims 1-19.

35 USC 112 REJECTION

In numbered paragraph 2 of the Office Action mailed April 19, 2005, claims 1-19 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-19 were rejected because the terms "regions" and "sections" were used. Claims 7, 8, 10, and 19 were rejected because they introduced additional elements.

Applicants have amended the claims to remove the terms "regions" and "sections." Applicants have cancelled claims 7, 8, and 10 and have amended claim 19 to remove the additional elements. Applicants believe that the amended claims now comply with the requirement of 35 U.S.C. 112, second paragraph, and that Applicants have provided a full and complete response to the 35 U.S.C. 112, second paragraph, rejection in numbered paragraph 2 of the Office Action mailed April 19, 2005.

35 U.S.C. 102 REJECTION

In the Office Action mailed April 19, 2005, Claims 1, 5, 6, 9-14 and 16-19 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by the Pourahmadi et al reference (International Patent No. WO 99/33559).

Applicants have amended claims 1-5 and 16-19 and have cancelled claims 6-15; therefore all the claims presented for examination are now in amended

form. Since the claims now appear in amended form the 35 USC §102(b) rejection in the Office Action mailed April 19, 2005 no longer applies.

Applicant believes the invention claimed in amended claims 1-5 and 16-19 is not anticipated by the Pourahmadi et al reference. The standard for a 35 USC §102 rejection is stated in RCA Corp. v. Applied Digital Systems, Inc, 221PQ 385, 388 (d. Cir. 1984) "Anticipation is established only when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention." Applicant points out that the following elements of Applicants' claims 1-5 and 16-19 are not found in the Pourahmadi et al reference:

> "a cutter having a tapered opening with a sharp edge for cutting the tissue," or
>
> "a specimen chamber connected directly to said biopsy region and located below said cutter, said specimen chamber positioned to directly receive the tissue cut by said cutter," or
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> "a specimen treatment and analysis chamber abutting and connected directly to said specimen chamber and located adjacent said specimen chamber," or
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> "a PCR reaction chamber directly abutting and connected directly to said specimen treatment and analysis chamber, said PCR reaction chamber constructed to receive the tissue from said specimen treatment and analysis chamber," or
>
> "said specimen treatment and analysis chamber having a chemical solution channel, an optical window, and an optical detection system," or
>
> "said sharp edge of said cutter has a smooth cutting edge with atomic sharpness capable of cutting very thin specimens of the tissue."

Since the elements described above are not found in the Pourahmadi et al reference, the Pourahmadi reference would not support a 35 USC §102(b) rejection.

The preamble in independent claims 1 and 16 now presented for examination uses the term "consisting of." The transitional phrase "consisting of" excludes any element not specified in the claim. (M.P.E.P. 2111.03) Applicants believe the invention claimed in amended claims 1- 5 and 16-19 now presented for examination is not anticipated by the Pourahmadi et al reference. The Pourahmadi et al reference includes the following combination of structure as recited in the Pourahmadi et al reference beginning at page 10, line 17 and continuing through page 13, line 2 set out below:

The Pourahmadi et al Reference

" Fig. 2 shows an example of a cartridge 101 according to a preferred embodiment of the invention. The cartridge is designed to process a fluid sample and amplify nucleic acids, such as by polymerase chain reaction (PCR). The cartridge 101 includes a sample port 103 for introducing a fluid sample into the cartridge and a sample flow path extending from the port 103 into the body of the cartridge.

The sample flow path includes a channel 105 leading from the sample part 103 to a mixing chamber 107 for mixing of the sample with lysing reagents. The sample flow path also includes a lysing chamber 119 where the sample contacts a filter to capture components, e.g., cells, spores, or microorganisms in the sample. The captured components are lysed in chamber 119. The sample flow path further includes a flow-through component 122 for capturing a desired analyte, e.g., nucleic acid, from the sample as the sample flows through the component 122.

The flow-through component 122 is preferably a microfabricated chip having a chamber with internal microstructures formed therein. The microstructures have sufficiently high surface area and binding affinity with the desired analyte to capture the analyte as the sample flows through the chip. The microstructures preferably comprise an array of columns integrally formed with at least one wall of the chamber and extending into the chamber. Various embodiments of the microfabricated chip are described in detail below with reference to Figs. 6-14.

In an alternative embodiment, the flow-through component 122 comprises a channel or chamber formed in the cartridge. The channel or chamber contains at least one solid support for capturing the desired analyte from the fluid sample as the sample flows through the solid

support. Suitable solid supports include filters, beads, fibers, membranes, glass wool, filter paper, polymers and gels.

The sample flow path also includes a channel 135 leading to flow controllers 41A and 41B, and a channel 136 leading to a vented waste chamber 139. The flow controllers 41A and 41B are arranged to direct the sample into the waste chamber 139 after the sample flows through the capture component 122.

The flow controllers 41A and 41B may be, e.g., valves, flow diverters, or fluid diodes.

A flow path for carrying elution fluid is also formed in the cartridge 101. In the preferred embodiment, the cartridge includes a storage chamber 127 for storing elution fluid.

The elution flow path extends from the chamber 127 through a channel 131 and passes through the flowthrough component 122, thereby releasing captured analyte from the component into the elution fluid. In an alternative embodiment, the cartridge includes a separate inlet port, in place of or in addition to the storage chamber 127, for introducing elution fluid into the cartridge from an external source.

The elution flow path diverges from the sample flow path after passing through the component 122. In this example, the elution flow path follows the channel 135 to the flow controllers 41A and 41B. The flow controllers 41A and 41B are arranged to direct the elution fluid and eluted analyte into a reagent chamber 141 containing PCR reagents. The reagent chamber 141 is in fluid communication with a reaction chamber 143 for PCR amplification.

The reaction chamber 143 may be a chamber formed in the cartridge 101. Alternatively, the reaction chamber 143 may be formed in a separate reaction vessel designed to be coupled to the cartridge to receive the eluted analyte.

Suitable reaction vessels for this purpose are disclosed in International Application Number PCT/US98/03962 filed March 2, 1998 and entitled "Heat Exchanging, Optically Interrogated Chemical Reaction Assembly", the disclosure of which is incorporated by reference herein. The application also teaches a thermal sleeve for receiving and thermally cycling the reaction chamber. For this reason, it is advantageous for the reaction chamber to protrude from the rest of the cartridge body to facilitate insertion of the reaction chamber into the thermal sleeve.

> The cartridge 101 also includes a storage chamber 109 for storing a lysing reagent, and a storage chamber 125 for storing a washing reagent. The cartridge 101 further includes flow controllers 123, such as valves or fluid diodes, for controlling the flow of fluid through the cartridge. The cartridge 101 also preferably includes resistive sensors 115 for sensing the presence of fluid in various channels and regions."

Applicants' invention defined by amended claims 1- 5 and 16-19 now presented for examination provides a combination of structure that produces a microfabricated biopsy and genetic analysis instrument that is compact, efficient, simple to operate, and is very different from the highly complex system disclosed in the Pourahmadi et al reference. Since the combination of elements of amended claims 1- 5 and 16-19 now presented for examination is not found in the Pourahmadi et al reference, the Pourahmadi et al reference would not support a 35 USC §102(b) rejection of amended claims 1- 5 and 16-19.

35 USC 103 Rejection

In numbered paragraph 8 of the Office Action mailed April 19, 2005 claims 2-4, 7, 8, 15, and 19 were rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over the primary Pourahmadi et al reference (International Patent No. WO 99/33559) in view of the secondary Krulevitch et al references (U.S. Patent No. 5,985,217 or U.S. Patent No. 6,319,474).

Applicants have amended claims 1-5 and 16-19 and have cancelled claims 6-15; therefore all the claims presented for examination are now in amended form. Since amended claims 2-4 and 19 now presented for examination appear in amended form the 35 USC §103(a) rejection in the Office Action mailed April 19, 2005 no longer applies.

Applicants believe that amended claims 2-4 and 19 now presented for examination are patentable and that the Pourahmadi et al and Krulevitch et al references would not support a 35 USC §103(a) rejection. The factual inquiries set

forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Pourahmadi et al reference and Applicants' invention defined by amended claims 2-4 and 19 now presented for examination includes the fact that the following elements of amended claims 2-4 and 19 now presented for examination are not found in the primary Pourahmadi et al reference:

> "a cutter having a tapered opening with a sharp edge for cutting the tissue," or
>
> "a specimen chamber connected directly to said biopsy region and located below said cutter, said specimen chamber positioned to directly receive the tissue cut by said cutter," or
>
> "a specimen treatment and analysis chamber abutting and connected directly to said specimen chamber and located adjacent said specimen chamber," or
>
> "a PCR reaction chamber directly abutting and connected directly to said specimen treatment and analysis chamber, said PCR reaction chamber constructed to receive the tissue from said specimen treatment and analysis chamber," or
>
> "said specimen treatment and analysis chamber having a chemical solution channel, an optical window, and an optical detection system," or
>
> "said sharp edge of said cutter has a smooth cutting edge with atomic sharpness capable of cutting very thin specimens of the tissue."

The Krulevitch et al references also fail to show the elements and combination of elements of amended claims 2-4 and 19 now presented for examination identified above. Since the Pourahmadi et al reference and the Krulevitch et al references fail to show the elements and combination of

elements, there can be no combination of the references that would show Applicant's invention defined by amended claims 2-4 and 19 now presented for examination and render them unpatentable.

There is no combination of the Pourahmadi et al reference and the Krulevitch et al references that would produce the combination of elements of Applicants' amended claims 2-4 and 19 now presented for examination. Further, there is no teaching of combining the Pourahmadi et al reference and the Krulevitch et al references to meet Applicants' amended claims 2-4 and 19 now presented for examination.

Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the references to produce Applicant's invention, a 35 U. S. C §103(a) rejection of Applicant's claims would not be appropriate.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated April 19, 2005 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,

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Livermore, California
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